

In the Requirement for Restriction dated May 2, 2008 the examiner has identified the following groups of inventions, as not so linked as to form a single general inventive concept under PCT Rule 13.1, and the examiner required election of a single invention identified below:

- **Group I, claims 1-4, 8, 10-13, 14 and 23-25** – drawn to a plasmid wherein two restriction enzyme recognition sites into which T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined [sic] only by one-step T-vector cloning, and a microorganism containing the expression vector;
- **Group II, claims 5-6, 9 and 19-22** – drawn to a pHCE-FOREX plasmid functioning as both a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHC vector, and a polynucleotide having AspEI restriction enzyme recognition;
- **Group III, claim 7** – drawn to methods of making a pHCE-FOREX plasmid function as both a T-vector and an expression vector
- **Group IV, claim 15** – drawn to an expression vector library, prepared by the method comprising the steps of: (a) removing the inserted polynucleotide by digesting the plasmid of claim 2, with the restriction enzyme selected from the group consisting of HphI, MboII, AspEI, and XcmI; and (b) inserting the library of various genes into a position from which the polynucleotide was removed;
- **Group V, claim 16** – drawn to an expression vector library wherein the library of various genes is inserted in the pHCE-FOREX-T vector; and
- **Group VI, claims 17-18** – drawn to method of determining the cloning of a target gene, comprising the transformation of microorganisms with the libraries of claim 15.

Applicants elect, with traverse, Group I, consisting of claims 1-4, 8, 10-13, 14 and 23-25, drawn to a plasmid wherein two restriction enzyme recognition sites into which T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganism containing the expression vector, class and subclass undefined.

### Traversal of Rejection

The examiner has made the above restriction based on the requirements of PCT Rule 13.1:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”).

As such, the examiner alleges that the above Groups do not possess unity of invention.

Applicants respectfully disagree and traverse the restriction.

Particularly, it is noted that, while claims 5-6, 9 and 19-22 do not depend from the claims of elected Group I, those claims are clearly a subset of the group identified in Group I as a “plasmid wherein two restriction enzyme recognition sites into which T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganism containing the expression vector.”

Claim 1, identified as a member of Group I recites:

1. A plasmid wherein two restriction enzyme recognition sites into which a T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning.

The examiner’s attention is respectfully drawn to claim 5, from which claims 6, 9 and 19-22 directly or indirectly depend. Claim 5 recites:

5. A plasmid (pHCE-FOREX) functioning as both a T-vector and an expression vector, wherein two AspEI restriction enzyme recognition sites are introduced at the downstream of the HCE promoter of the pHCE vector, and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites.

Clearly these two claims and the claims that depend therefrom are so related as to form a general inventive concept under the requirements of PCT Rule 13.1. The examiner’s attention is respectfully drawn to the following table illustrating the common features of claims 1 and 5:

<u>Claim 1</u>	<u>Claim 5</u>
A plasmid	A plasmid (pHCE-FOREX)

<b><u>Claim 1</u></b>	<b><u>Claim 5</u></b>
two restriction enzyme recognition sites into which a T- vector can be cloned	two AspEI restriction enzyme recognition sites
are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell	are introduced at the downstream of the HCE promoter of the pHCE vector,
whereby the plasmid functions as both the T-vector and an expression vector	functioning as both a T-vector and an expression vector
and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning	
	and a polynucleotide having AspEI restriction enzyme recognition sites at its both ends is inserted between the two AspEI restriction enzyme recognition sites

As such, applicants assert that Groups I and II are so linked as to form a single general inventive concept and, under PCT Rule 13.1 possess unity of invention. Accordingly, the requirement for restriction is traversed and examination of claims 1-6, 8-14, and 19-25 of the invention together is requested.

Even if all of the above-identified groups are not so linked as to form a general inventive concept, search of all 25 claims of the application would not pose a serious burden on the examiner if restriction is not required. Groups I and II are so related as set forth above and rejoinder is requested for examination. Groups III-VI contain only 5 claims additional to those identified in Groups I and II. Therefore, including Groups III-VI with Groups I and II would require search of only five additional claims.

### **Rejoinder**

In the event that the restriction requirement between the composition and method aspects of the invention is made final, Applicants responsively request rejoinder of method claims 7 and 15-18 under the provisions of MPEP §821.04 upon confirmation of allowable subject matter of the composition claims 1-6, 8-14, and 19-25.

Such rejoinder would be fully proper under these circumstances<sup>1</sup>.

In the present application the elected claims 1-4, 8, 10-14, 23-25 and claims 5-6, 9, and 19-22 requested to be rejoined for examination are directed to plasmids and the remaining claims 7 and 15-18 are directed to methods for making and methods for using such plasmids.

Consistent with the provisions of the MPEP §821.04, when the product claims 1-6, 8-14, and 19-25 are subsequently found allowable, any withdrawn method of making and/or using claims of Groups III to VI would be properly rejoined for examination.

### CONCLUSION

In response to the Requirement for Restriction dated July 31, 2006, Applicants have provisionally elected, with traverse, Group I, claims 1-4, 8, 10-13, 14, and 23-25, drawn to a plasmid wherein two restriction enzyme recognition sites into which T-vector can be cloned are introduced at the downstream of a promoter of a vector that is constantly expressed at high levels regardless of the kind of a host cell, whereby the plasmid functions as both the T-vector and an expression vector, and has the property of allowing the expression of a target gene to be examined only by one-step T-vector cloning, and a microorganism containing the expression vector, class and subclass undefined.

The examiner correspondingly is requested to reconsider the election requirements in light of the foregoing remarks.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

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<sup>1</sup> When an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, Applicants may present claims directed to the process of making and/or using the patentable product for examination through the rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

Respectfully submitted,

Date: June 2, 2008

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